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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/177,843 10/22/98 LOIKE

J 48940-A-PCT-

EXAMINER

HM22/0130

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BANSAL, G

ART UNIT

PAPER NUMBER

1642

12

DATE MAILED:

01/30/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/177843

Applicant(s)

Lorke et al

Examiner

Gertie Bausel

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 11/6/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-39, 41-54 is/are pending in the application.
- ☐ Of the above claim(s) 1-26, 42-54 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 27-39, 41 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2 sheets
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1642

### **DETAILED ACTION**

1. Applicant's amendment filed November 6, 2000 (Paper No:10/B) is acknowledged. Accordingly, claims 27, 39, 41 have been amended, and claim 40 has been cancelled.

Claims 27-39, 41 are being examined.

### ***Response to Arguments***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejection of claim 27-38 under 35 U.S.C. 112, 2nd paragraph is maintained as set out in the previous office action. Applicant's arguments have been considered but they are not deemed to be persuasive.. Applicant argues that "agent" is not indefinite as the specification clearly defines the term as "wherein the agent binds to a  $\beta 1$  integrin cell surface receptor". However, the specification at the cited section defines the antibody as being contemplated to have the specified functional limitation. The amendment to the claim still does not clarify or render definite the metes and bounds of "agent", which in a broad sense can be **any** molecule that will bind to the  $\beta 1$  integrin cell surface receptor. The "any" can include various chemical moieties (organic molecules, inorganic molecules, nucleic acids etc etc. or even peptide molecules of varied structures).

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 U.S.C. § 112***

- 4.A. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 27-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody and binding fragments thereof and peptide GRGDSP, does not reasonably provide enablement for any and all agents for binding to  $\beta 1$  integrin cell surface receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims are drawn to a method of treating a malignant tumour by administering an agent which binds to a  $\beta 1$  integrin cell surface receptor to enhance migration of leukocytes through tenascin to reach tumour cells and kill them. The specification discloses the administration of anti- $\beta 1$  integrin antibodies or peptide GRGDSP were able to allow migration of leukocytes. The specification does not provide sufficient guidance as to other agents, peptidomimetics, peptides or how to begin to select the compounds to be tested. As Applicant points out, the assays may be available, but there is no teaching provided nor working example that would lead one of skill in the art to begin to look for "agent" which binds to  $\beta 1$  integrin cell surface receptor wherein it binds to that can be tested in this area as the list would be enormously long and varied. One of skill in the art would be forced into undue experimentation to practice the claimed invention as broadly claimed.

4.B. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 41 depends from a cancelled claim and hence is indefinite.

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

7. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 25, 2000



**GEETHA P. BANSAL  
PRIMARY EXAMINER**